



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/517,908	01/30/2006	Akio Wakabayashi	AKIOWAK.006NP	6878
20995 7590 11/09/2007 KNOBBE MARTENS OLSON & BEAR LLP 2040 MAIN STREET FOURTEENTH FLOOR IRVINE, CA 92614			EXAMINER ANDERSON, MICHAEL J	
			ART UNIT 3767	PAPER NUMBER
			NOTIFICATION DATE 11/09/2007	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

jcartee@kmob.com
eOAPilot@kmob.com

Office Action Summary

Application No.

10/517,908

Applicant(s)

WAKABAYASHI, AKIO

Examiner

Michael J. Anderson

Art Unit

3767

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 August 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5,7-22 and 24-29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5,7-22 and 24-29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 7-9, 15 and 24-25 are rejected under 35 U.S.C. 102(b) as being anticipated by Yarger USPN 5,360,414.

In regards to claims 1, 2 and 15, Yarger ('414) discloses A drainage device (20) for draining unwanted matter from a body cavity of an animal, comprising a tube (22) having first and second ends (figure 1), a first end adapted to connect (24, 44) to a vacuum source of at least approximately 50 torr, and a second end adapted to be inserted into a body cavity of an animal. a plurality of holes (28) formed into a wall of an insertion portion of the tube, the insertion portion of the tube configured to be inserted into a body cavity of an animal, each of the plurality of holes communicating a respective suction force from an inner bore of said tube to matter outside said tube, the area of each of the plurality of holes selected such that each of the respective suction forces is insufficient to cause injury to proximate body tissues within a body cavity of an animal Figures 6-15 and Col. 7, lines 28-68). Wherein said animal is a human (Col. 4, lines 34-43).

In regards to claims 1, 15, 7-9, 20 and 24-25, Yarger ('414) discloses each hole is approximately circular and has an area no greater than that of a circle having a diameter of around one half of an internal diameter of said tube (Col. 6, lines 14-19).

Each hole has an area no greater than that of a circle having a diameter of 1 mm or has an area no greater than that of a circle having a diameter of .5 mm (Col. 5, lines 2-7).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 3-5, 11-12, 16, 19, 22, and 26-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yarger ('414) in view of Breznock USPN 6,638,253 B2. Yarger ('414') discloses a drainage device for removing fluid from a body cavity with the limitations as recited above. However, Yarger lacks the teachings of wall thickness to maintain structural integrity of a tube connected to a vacuum source, a defined number of holes to allow passage of fluids, a one-way valve located in a connector on the tube that permits flow of gas or fluid from the body cavity toward vacuum source, and a vacuum source of approximately 100 torr. Breznock ('253) discloses a drainage device

for a chest cavity with tubing material and wall thickness designed to maintain structural integrity of a tube connected to a vacuum source, sufficient numbers of holes to allow passage of fluids, a one-way valve to allow unidirectional flow of gas or fluids from the cavity towards the vacuum source of approximately 100 torr. It would have been obvious to one of ordinary skill in the art to modify the drainage device of Yarger ('414) with the tubing materials, one-way valve and a vacuum source of approximately 100 torr of Breznock('253) to prevent the drainage tube from collapsing from vacuum pressure and prevent gas or fluids from re-entering the cavity from the vacuum source.

Concerning claims 3-5, Breznock ('253) discloses a drainage device for a chest cavity (Col. 8, lines 21-22) with a thickness of the wall of a tube is selected to maintain the structural integrity of the tube when a first end of the tube is connected to a vacuum source of approximately 100 torr or greater (Col. 4, lines 32-52) and at least 100 holes are formed into the wall of a tube (figure 1 and Col. 4, lines 64-67 and Col 5, lines 1-5).

Concerning claims 11-12, 16, 19, 22 and 27, Breznock ('253) discloses a one-way valve (14) located between an insertion portion of a tube and a vacuum source, permitting flow of gas or fluid through the one-way valve from a body cavity toward a vacuum source (Figure 1 and Col. 9, lines 22-24). A one-way valve located in a connector (15) interposed between the tube and vacuum source, the connector having a first end adapted to be connected to said first end of said tube, and a second end adapted to be connected to a vacuum source of at least about 50 torr (Figures 1 and 5A and Col. 8, lines 28-37).

Concerning claim 26, Breznock ('253) discloses a means for regulating a respective suction force applied at each of a multiplicity of locations such that each of a respective suction forces is incapable of injuring' bodily tissue exposed within a body cavity (Col. 8, lines 28-37).

Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Yarger ('414) in view of Cambron USPN 6,017,493. Yarger ('414') discloses a drainage device for removing fluid from a body cavity with the limitations as recited above. However, Yarger lacks the teaching of a specific size of a tube to be used in the drainage device. Cambron ('493) discloses various sizes of catheter tubes to be used in a drainage system under vacuum- assisted conditions. It would have been obvious to one of ordinary skill in the art to modify Yarger's drainage system with the catheter tube sizes of Cambron to allow safe and proper drainage from a cavity. The smallest catheter tube would have been obvious to use as this would pose the least invasive and the safest for the well being of the patient. Concerning claim 10, Cambron ('493) discloses catheter tubes in the sizes of 20F (French) or smaller for use in vacuum-assisted drainage devices (Col. 8, tables 3 and 4).

Claims 13-14, 17-18, 20-21, and 28-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yarger ('414) in view of Wakabayashi USPN 6,352,525 B1. Yarger ('414') discloses a drainage device for removing fluid from a body cavity with the limitations as recited above. However, Yarger lacks a vacuum chamber with a gas outlet port, inlet port, fluid drainage port and a vacuum relief valve. Wakabayashi ('525) discloses a vacuum chamber with a gas outlet port, inlet port, fluid drainage port and a

vacuum relief valve for the use in a chest drainage system. It would have been obvious to one of ordinary skill in the art to modify Yarger's drainage device with Wakabayashi's vacuum chamber and vacuum pump housing to provide a vacuum source to efficiently and safely remove fluids from a body cavity to a collection reservoir.

Concerning claims 13-14, 17-18 and 20-21, Wakabayashi ('525) discloses a vacuum chamber (302) having a gas outlet port (514) adapted to be connected to a vacuum source of at least about 50 torr. A vacuum chamber having an inlet port (508) connected to a first end of a tube communicating a suction force from the gas outlet port to the first end of a tube. A fluid drainage outlet port (108) through which fluid matter from a body cavity flows in a direction away from a body cavity. A vacuum relief valve (637) included in a vacuum chamber, opening to direct atmospheric air into a vacuum chamber when a vacuum pressure inside a vacuum chamber exceeds a predetermined threshold.

Concerning claims 28 and 29, Wakabayashi ('525) discloses a means for maintaining vacuum pressure in a high pressure, high efficiency body cavity drainage system at a predetermined level by allowing atmospheric air to enter said drainage system when a vacuum pressure in a drainage system exceeds a predetermined level. A means for separating fluids drained from a body cavity from gases drained from a body cavity (Col. 13, lines 32-67 and Col. 14, lines 9-32).

Response to Amendment

The present communication responds to the Amendment of 08/31/2007.

By this communication, claims 1, 15, and 20 were amended and claims 6 and 23 were canceled. The amendments did not add new matter. Claims 1-5 7-22 and 24-29 are pending. The rejection(s) are as stated.

Response to Arguments

Applicant's arguments filed 8/31/2007 have been fully considered but they are not persuasive. With regards to applicant arguments concerning claims 1, 2, 6-9, 15 and 23-25 that the high vacuum pressure be at least 50 torr. Yarger discloses a general vacuum source (column 4, line 15-19) and Breznock discloses (column 8, line 30-35) that a typical low level vacuum source works in the range of 1 to 100 torr. The low or high vacuum pressure ranges are readily available in the vacuum pump art.

With regards to applicant arguments concerning amended claims 1, 7, 15 and 20 that each hole have a specific size. Yarger discloses (column 6, lines 14-19) hole sizes that are inclusive of the specific size required in the claims.

With regards to applicant arguments concerning claims 3-5, 11-12, 16, 19, 22 and 26-27 that the vacuum pressure be approximately 100 torr. Breznock discloses (column 8, line 30-35) that a typical low level vacuum source works in the range of 1 to 100 torr. The low or high vacuum pressure ranges are readily available in the vacuum pump and tube art.

With regards to applicant arguments concerning claim 5 that the tube have at least 100 holes, Breznock discloses "holes 20 are of sufficient size and quantity" which puts no limit on the total number of holes.

With regards to applicant arguments concerning claim 26, that the suction force be regulated at each hole, Breznock discloses (column 8, lines 28-37) such a regulation of vacuum pressure that would impact each hole. Reducing the vacuum pressure would reduce injury risk.

With regards to applicant arguments concerning claim 10 that one skilled in the art would not have combined Yarger and Cambron and that the Office has not given a satisfactory reason to combine the two disclosures, the Office disagrees.

With regards to applicant arguments concerning claims 13, 14, 17, 18, 21, 28 and 29 that depend from amended claims 1, 15 and 20. Arguments for amended claims 1, 15 and 20 have been address above.

Conclusion

References considered pertinent to Applicants' disclosure are listed on form PTO-892. All references listed on form PTO-892 are cited in their entirety.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael J. Anderson whose telephone number is (571) 272-2764. The examiner can normally be reached on M-F 6:30 am to 3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin C. Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Michael J Anderson

Application/Control Number: 10/517,908
Art Unit: 3767

Page 10

Examiner
Art Unit 3767

MJA
11/5/2007

KEVIN C. SIRMONS
SUPERVISORY PATENT EXAMINER

A handwritten signature in cursive script, reading "Kevin C. Sirmons".